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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,950	07/19/2001	Robert C. Getts	4081.006	1927

7590 10/16/2008

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/908,950	GETTS ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2008 has been entered.

Status of the Application

2. The action is in response to the RCE filed on July 23, 2008. Currently claims 1-58 are pending. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in-part for the reasons that follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-3, 7-8, 17, 18-22, 25-26, 35-58, are rejected under 35 U.S.C. 103(a) as being unpatentable over Skouv (US 6, 303,315) in view of Gerhart et al. (J cell Biology, Vol. 149, No. 4, May 15, 2000).

Skouv teaches a method and composition of claims 1, 19, 47, 50 comprising

Incubating a first component comprising RNA extracted from a sample said RNA comprising a capture sequence and a target specific sequence (see col. 10, line 37-41,col. 7, line

44-56, col. 3, line 32-61); and hybridizing said first component with a microarray comprising plurality of probes (see col. 5, line 27-46) and incubation at a temperature that facilitates hybridization and detecting the hybridization pattern (see col.9, line 14-50).

With regard to claim 7-8, 25-26, 51, 56, Skouv teaches that the capture sequence of said RNA is single stranded oligonucleotide consisting of poly A sequence and a sequence that is complementary to the capture sequence comprises at least one thymine base (see col. 10, line 37-41,col. 7, line 44-56, col. 3, line 32-61col. 17, line 15-23).

With regard to claim 15, 31, Skouv teaches that microarray comprises oligonucleotides (see col. 5, line 27-46).

With regard to the claim 11-12, 32, 17, 36, 58, Skouv teaches suitable temperature and time for sufficient hybridization and also teach after hybridization the microarray is washed to remove unhybridized probe (see col. 9, line 14-29).

With regard to claims 18, 35, 37-42, Skouv teaches that the probe sequences comprise DNA and RNA and LNA , and LNA act as blocking nucleotide sequences (see col. 2, line 22-67).

With regard to claim 57, Skouv teaches that the composition and the method comprises RNAse inhibitor (see col. 10, line 53-63).

However Skouv did not specifically teach dendrimers having multiple arms.

Gerhart et al. teach a nucleic acid detection method comprising the use of dendrimers having multiple single-stranded arms (see page 825, col. 2, paragraph 1, page 826, Fig. 1, col. 1, line 1-13). Gerhart et al. also teach that the dendimer comprises multiple first arms comprising a

label and second arms comprising target specific sequences complementary to capture RNA (see page 826, col. 1, paragraph 2 under materials and methods).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for detecting a nucleic acid as taught by Skouv with a dendrimer having multiple arms as taught by Gerhart et al. to achieve expected advantage of developing an enhanced sensitivity of detecting a target nucleic acid. An ordinary practitioner would have been motivated to combine the method of Skouv with the step of adding dendrimer as taught by Gerhart et al. for the purpose of increasing the sensitivity of detecting a target nucleic acid by signal amplification and reducing the background noise. An ordinary person skilled in the art would have a reasonable expectation of success that would result in reducing background noise and amplification of the signal because Gerhart et al. explicitly taught that the use of dendrimeric probe having multiple arms bearing labels would improve or enhance the signal and minimizes the back-ground noise in hybridization and improves the detection of low abundant mRNA (page 825, col. 2, paragraph 1, page 826, col. 1, line 1-13, page 831, col. 1, paragraph 1under discussion section) and such a modification of the method is considered as obvious over the cited prior art.

B. Claims 4-6, 9-16, 23-24, 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skouv (US 6, 303,315) in view of Gerhart et al. (J cell Biology, Vol. 149, No. 4, May 15, 2000) as applied to claims 1-3, 7-8, 17, 18-22, 25-26, 35-58 above, and further in view of Van Ness et al. (USPN. 6,361,940).

Skouv in view of Gerhart et al. teach a method for determining the presence of a specific nucleotide sequence as discussed above in section 3A.

However, neither Skouv nor Gerhart et al. teach hybridization temperatures ranging from 50-60^0 C, incubation time, and base solution to separate and purge the hybridized RNA reagent.

Van Ness et al. teach a method for enhancing hybridization and probing or priming specificity, wherein Van Ness et al. teach parameters of a thermal melting profiles (helical coil transition) of an oligonucleotide in hybridization solutions (hybotropic or salt solutions used for separating and purging of hybridized complexes from an array) and the dependency of temperatures (discrimination temperatures) based on the base composition and G-C content of the oligonucleotide probes ranging from 0- 80^0 C (see col. 34, line 48-67, col. 35, line 1-45, col. 45, line 4-33). With regard to claims 4, 6, 22, 24, Van Ness et al. also teach the base solution is sodium hydroxide (see col. 66, line 10-14); With regard to claims 13, 15, 29, 31, Van Ness et al. teach that the probe nucleotide sequences on microarray comprise oligonucleotides and cDNA sequences (see col. 66, line 21-40).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for determining the presence of a specific nucleotide sequence as taught by Skouv in view of Gerhart et al. with a the parameters that enhance hybridization specificity such as incubation temperatures and hybridization solutions as taught by Van Ness et al. to achieve expected advantage of developing an enhanced sensitivity and specificity of detecting a target nucleic acid. An ordinary practitioner would have been motivated to combine the method of Skouv in view of Gerhart et al. with the step of adding said hybridization parameters as taught by Van Ness et al. for the purpose of increasing the specificity of hybridization assay. An ordinary person skilled in the art would have a reasonable expectation

of success that such modification would result in enhance specificity of hybridization signal because Van Ness et al. explicitly taught that the parameters to optimize hybridization conditions and to increase hybridization specificity (col. 56, line 52-67, col. 57, line 1-16). Such modification is considered as obvious over the cited prior art. Further, selection of specific hybridization conditions including incubation time, temperatures, oligonucleotide probes represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Van Ness et al. As noted in *In re Aller*, 105 USPQ 233 at 235,More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-5, 9-17, 19-23, 27-36 43-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 18 and 22-23, 27-42 of copending Application No. 09/802,162 (Pub No. US 2002/0051981 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim 1-3, 19-21, 43-49 are generic to all that is recited in claims 1-11 and 18-22 of the co-pending application. That is, the claims 1-11, 18 and 22 of the co-pending application fall entirely within the scope of the instant claims 1-3, 19-21, 43-49 or in other words, the instant claims 1-3, 19, 43-49 are anticipated by the claims 1-11, 18 and 22 of the application. Specifically the method of steps (1)- (4) of the claim 1 in combination with 2, and the method steps (1) – (3) of claim 18 in combination with claims 22, comprising a mixture of cDNA reagent (which comprises mRNA) having a capture sequence, a dendrimer and a microarray with plurality of features (nucleic acid sequences), are within the scope of the instant claims 1-3, 19-21, 43-49. Further the instant claims 4-5, 9-12, 14-17, 19-23, 27-36 are generic to all that is recited in claims 5-9, 11, 27-42 of the co-pending application, that is, the claims 5-9, 11, 27-42 of the co-pending application fall entirely within the scope of the instant claims 4-5, 9-12, 14-17, 19-23, 27-36. Thus the instant claims encompass the claims in the co-pending application and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method is obvious over the claims in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

5. With regard to the rejection of claims 33-35, under 35 USC 112, second paragraph, Applicant's arguments and amendment were fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment.

6. With regard to the rejection of claims under 35 USC 103(a) and double patenting, Applicants' arguments were fully considered and the rejections are withdrawn herein and new rejections are set forth as above.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637